(2) Name, title, address, telephone number, signature, and date of signature of the person making the certification;

(3) Name, address, and FDA registration number or FDA assigned identification number for the distributor covered by the certification, and the number of reports submitted for devices distributed by the distributor;

(4) A statement certifying that:

(i) The individual certifying for the firm has read the MDR requirements under part 804;

(ii) The firm has established a system to implement MDR reporting;

(iii) Following the procedures of its MDR reporting system, the firm submitted the specified number of reports, or no reports, during the certification period; and

(iv) The certification is made to the best of the certifying official's knowledge and belief.

[62 FR 13306, Mar. 20, 1997]

§ 804.31 Additional requirements.

Requests for additional information. If FDA determines that the protection of the public health requires information in addition to that included in the medical device reports submitted to FDA under this part, the distributor shall, upon FDA's request, submit such additional information. Any request by FDA under this section shall state the reason or purpose for which the information is being requested, and specify a due date for the submission of such information.

§ 804.32 Supplemental information.

(a) Only one MDR is required under this part if the distributor becomes aware, from more than one source, of information concerning the same patient and the same event.

(b) An MDR that would otherwise be required under this section is not required by the distributor if:

(1) The distributor determines that the information received is erroneous in that a death, serious injury, serious illness, or the malfunction did not occur; or

(2) The distributor determines that the information received is erroneous in that the device that is the subject of the information was distributed by another distributor. A distributor shall forward to FDA any report that is erroneously sent to the distributor, with a cover letter explaining that the product in question is not distributed by that firm.

(c) A report or information submitted by a distributor under this part (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the party submitting the report or by FDA that the report or information constitutes an admission that the device, the establishment submitting the report, or employees thereof, caused or contributed to a death, serious injury, serious illness, or malfunction. A distributor need not admit, and may deny, that the report or information submitted under this part constitutes an admission that the device, the party submitting the report, or employees thereof, caused or contributed to a death or serious injury, serious illness, or malfunction.

§ 804.33 Alternative reporting requirements.

(a) Distributors may request exemptions from any or all of the reporting requirements in this part. These requests are required to be in writing and to include both the information necessary to identify the firm and device and an explanation why the request is justified.

(b) FDA may grant a distributor, in writing, an exemption from any or all of the reporting requirements in this part and may change the frequency of reporting to quarterly, semiannually, annually, or other appropriate time periods. In granting such exemptions, FDA may impose other reporting requirements to ensure the protection of public health and safety. FDA may also authorize the use of alternative reporting media such as magnetic tape or disk, in lieu of FDA forms.

(c) FDA may revoke alternative reporting options, in writing, if FDA determines that protection of the public health justifies a return to the requirements as stated in this part.

§ 804.34 Written MDR procedures.

Device distributors shall maintain and implement written MDR procedures in the following areas: